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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,180

11/23/2005

Carlos Alberto Genaro Mammarella

GBA-002

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

07/01/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/526,180

**Applicant(s)**MAMMARELLA, CARLOS  
ALBERTO GENARO**Examiner**

Gollamudi S. Kishore, Ph.D

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3-21-05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group I, claims 1-9 in the reply filed on 4-16-09 is acknowledged.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to how cholesterol can be considered as a saturated lipid and cholesterol by itself does not form liposomes. The distinction between 'phosphatidylcholine' and 'natural phosphatidylcholine' is unclear. Also unclear is whether the limitation in parenthesis is indeed the limitation. Furthermore, natural phosphatidylcholines such as soy and egg are not saturated.

#### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Needham (US 2002/0102298).

Needham discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed

Art Unit: 1612

active agents (Fig. 4, 0040, 0043, 0048, 0072, 0085 and examples). The compositions further contain DSPE-PEG).

Note: The 102 (b) rejection will be reconsidered upon submission of the English translation of the priority paper.

5. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 99/65466.

WO discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, pages 7, 9, 13, 16 and examples). The compositions further contain DSPE-PEG (page 10).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Needham or WO 99 cited above.

Needham as discussed above discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts

Art Unit: 1612

and claimed active agents (Fig. 4, 0040, 0043, 0048, 0072, 0085 and examples). The compositions further contain DSPE-PEG).

WO discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, pages 7, 9, 13, 16 and examples). The compositions further contain DSPE-PEG (page 10).

Needham and WO however, do not specifically teach as to how much of doxorubicin is encapsulated. The amount of the active agent incorporated within the liposomes depends upon various parameters such as the method of loading and the severity of the disease and therefore, deemed to be an obvious parameter manipulatable by an artisan.

7. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Needham or WO cited above in combination with O'Brien (US 2002/0064554).

Needham as discussed above discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, 0040, 0043, 0048, 0072, 0085 and examples). The compositions further contain DSPE-PEG). Needham however, does not specify whether the PEG-DSPE is a methylated PEG-DSPE.

WO discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, pages 7, 9, 13, 16 and examples). The compositions further contain DSPE-PEG (page 10).

O'Brien while disclosing liposomal formulations teaches that either PEG or methyl PEG can be used to couple with phosphatidylethanolamine (0008).

Assuming that PEG-DSPE taught by Needham or WO is not methylated PEG-DSPE, it would have been obvious to one of ordinary skill in the art to use methyl PEG to couple to PE with a reasonable expectation of success because of the equivalency taught by O'Brien.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore /  
Primary Examiner, Art Unit 1612

GSK